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Cheetah Medical
10291 N. Meridian,
Suite 100
Indianapolis, IN 46290
USA

SECTION 5: 510(k) Summary

JAN 18 2008

Submitter

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Contact Person

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Date Prepared

January 10, 2008

Device Information

Trade name: **Cheetah NICOM System**

Common name: **Cheetah NICOM**

Classification Name: **Pre-Programmable Diagnostic Computer** (21 CFR 870.1435, Product Code: DXG; 21 CFR 870.2360 Product Code DRX)

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Devices to which substantial equivalence is claimed:

The Cheetah NICOM system was found substantially equivalent to the VLIGILANCE CCO/CEDV 7 VIGILANCE CCO/SVO_2/CEDV Monitor (K000664) under K042144.

The NICOM Electrodes are substantially equivalent to the electrodes cleared for marketing with the original NICOM Monitoring System (K042144), when used with the NICOM system. The electrodes cleared in the original submission were the Red Dot™ electrodes by 3M Health Care.

Device Description:
The Cheetah NICOM is a portable, non-invasive, Cardiac Output detector system. The NICOM system measures the Cardiac Output by employing the electrical bio-impedance measurement technique. Electrical bio-impedance is the characteristic impedance of a volume of tissue and fluid. In the case of Cardiac Output measurements, the relevant tissue includes the heart and the immediate surrounding volume of the thorax. The relevant fluid is blood.

Cheetah Medical's NICOM electrode is a double electrode sticker. Within each sticker, one electrode is used to inject a high frequency sine wave into the body, while the resulting voltage is measured at the adjacent electrode. An array of such electrodes is placed at specific areas of the thorax, the impedance to the current flow calculated, and the electrical bio-reactance waveform constructed.

Indications for Use:
The Cheetah NICOM system is a portable, non-invasive Cardiac Output monitoring device based on bio-impedance Cardiography. The Cheetah NICOM system is intended to monitor and display a patient's Cardiac Output in units of Ltr/Min, and was cleared under K042144.

NICOM Electrodes are disposable electrodes used in conjuction with he NICOM signal processing product line.

Brief Description of Non-Clinical Testing

1. Electrodes were tested per ANSI/AAMI EC12:2000/(R)2005; Disposable ECG electrodes, 3ed.
2. Biocompatibility was confirmed per ISO-10993 standard; Biological Evaluation of Medical Devices.

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Brief Description of Clinical Testing

NICOM Electrodes were tested on:

1. 119 consecutive patients requiring PAC in the immediate postoperative period following cardiac surgery - No adverse events were reported.
2. 36 patients undergoing cardiac output evaluation during stress testing in Lonestar Heart Center, Amarillo, Texas, US. No adverse events were reported.
3. Cardiac output was measured in 10 subjects with the NICOM System using the NICOM electrodes and using the 3M Health Care Red Dot electrodes. The results demonstrate that the NICOM electrodes are substantially equivalent to the 3M Health Care Red Dot electrodes when used with the NICOM System.

Conclusion

The NICOM Electrode is a dual electrode sticker, used in conjunction with its NICOM system to monitor cardiac output by measuring electrical impedance changes in the thorax region. The Cheetah NICOM system is intended for prescription use only.

NICOM electrodes were extensively tested (bench, animal, clinical) and proved to be safe and effective.

The data demonstrate that the NICOM electrodes are substantially equivalent to the 3M Red Dot Electrodes that were cleared with the original NICOM System (K042144) when used with the NICOM system.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Cheetah Medical
c/o Ms. Rhona Shanker
Z & B Enterprises, Inc.
12154 Darnestown Road # 236
Gaithersburg, MD 20878

Re: K071631
Cheetah NICOM System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function preprogrammed diagnostic computer
Regulatory Class: Class II (two)
Product Code: DXG
Dated: June 14, 2007
Received: June 14, 2007

Dear Ms. Shanker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volchmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4: Indications for Use

510(k) Number: K071631

Device Name: Cheetah NICOM System

Indications for Use:

The Cheetah NICOM system is a portable, non-invasive Cardiac Output monitoring device based on bio-impedance Cardiography. The Cheetah NICOM system is intended to monitor and display a patient's Cardiac Output in units of Ltr/Min, and was cleared under K042144.

NICOM Electrodes are disposable electrodes used in conjunction with the NICOM signal processing product line.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

10(k) Number K071631